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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,666	09/28/2001	Suzanne De La Monte	0609.4370003/RWE/FRC	3650

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EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,666	DE LA MONTE ET AL.	
	Examiner	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,20-30 and 32* is/are rejected.

7)☒ Claim(s) *19 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 17, 18, 20-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over de la Monte et al [WO 94/23756]. This rejection is maintained for the reasons set forth in the Official action mailed 08/08/2003.

The instant invention is drawn to various antisense based compounds targeted to to an mRNA that corresponds to nucleotides 150-1139 of SEQ ID NO: 1. The compounds are antisense oligonucleotides, ribozymes, triplex forming oligonucleotides and external guide sequences.

The de la Monte reference is drawn to the same target nucleic acid as the instant invention. The disclosure of de la Monte et al teaches making the same molecules as the instant invention but do not limit the target range to nucleotides 150-1139 of instant SEQ ID NO: 1. It is noted that the work of de la Monte et al is that of the instant inventors where it has been asserted in the instant specification that there were sequencing errors in WO 94/23756 where the instant sequence SEQ ID NO: 1 corrects those sequencing errors. However, it was clearly taught in applicants earlier document [Wo 94/23756] to make the same molecules now claimed across the entire mRNA of the "incorrect sequence" reported in the WO patent. However it is noted that a comparison (see attached sequence alignment of the instant SEQ ID NO: 1 and its corresponding sequence in WO 94/23756) of the sequence in WO 94/23756 clearly shows that there is sufficient similarity in the sequences that, by following the teachings of WO 94/23756, one would clearly have made antisense compounds as instantly

claimed with the region instantly recited. Further it is noted that WO 94/23756 indicates at page 56 and 85 that a deposit of the AD10-7-DH1 was made to the ATCC under accession number 69262 which is the source of the errored sequence in WO 94/23756 and the "corrected" sequence of the instant application (see page 5 of the instant specification). Since the teachings (see pages 46-56, and claims 73-88, for example) of de la Monte et al parallel those of the instant specification in the design and production of the claimed antisense oligonucleotides, ribozymes, triplex forming oligonucleotides, and external guide sequences and since the sequence reported as "corrected" in the instant specification is so similar to that disclosed as errored in WO 94/ 23756 and further where the source of the correct sequence was available at the time of invention, one in the art would clearly have made antisense oligonucleotides, ribozymes, triplex forming oligonucleotides, and external guide sequences within the region instantly recited. The region instantly recited deletes the first 149 nucleotides of the target nucleic acid and has been eliminated as a target solely because it was not incorrectly sequenced (see page 25 of the instant specification, for example). The teachings of de la Monde et al clearly teach making the compounds over the entire target sequence and clearly some of these would fall within the range instantly recited (see pages 46-56 and claims 73-88, for example).

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Applicant's arguments filed 11/07/03 have been fully considered but they are not persuasive.

Applicant argues that because the sequences of the instant applicantion and that of the cited prior art contain "positions of non-identity", the claimed invention can not ba found obvious. Applicant asserts that the prior art teaches to target only those regions of the prior art sequence that are not homologous to the PTP sequence. Applicant then asserts that one in the art would be discouraged from making antisense compositions that are homologous to PTP. Applicant asserts that one in the art would have been discouraged from making antisense due to their homology to PTP sequences.

The prior art then at least does teach to make antisense to those regions of the prior art sequence that are not homologous to PTP, for example.

Applicant asserts that the statement of a preferred antisense oligonucleotide being targeted to the 5' end of the prior art sequence would have taught away from targeted within nucleotides 150-1139 of the instant SEQ ID NO: 1. It is not agreed that the pointing to a preferred region teaches away from others. It merely indicates that one region may be more desirable than another, but does not necessarily indicate that other regions are undesirable.

Applicant asserts that there is nothing that specifies targeting within the region of 150-1139 of SEQ ID NO: 1. It is noted that the prior art teaches to target any sequence, including that instantly specified, that does not have homology to PTP. It has been taught therefore to target regions that are embraced within the region now recited.

Applicant argues the "69 positions of non-identity" and assert that the selection of any at these positions would lead to antisense compositions outside the scope of the claimed invention. It is noted that those regions that are not one of the "69 positions of non-identity" and are not regions that are homologous to PTP would clearly be regions taught in the prior art to be targeted and would, when targeted as taught in the prior art, be within the scope now claimed. It is noted that at page 26 of the instant specification, antisense compounds targeted to sequences non-homologous to PTP are specifically contemplated and are clearly embraced within the scope of the instant invention and that taught in the prior art. It is also noted that applicant terminology of "69 positions of non-identity" could also be stated as 34 regions of non-identity since the 69 positions make up 34 regions, for example. When one in the art views the sequence alignment between the prior art sequence and the instant corrected sequence, it is apparent that there are large areas of targetable sequence that are identical, and it is clear that one following the teachings of the prior art (even with the "uncorrected sequence") would be led to make antisense within the scope of those instantly claimed.

Applicant assertion that the AD10-7 of the prior art not necessarily being the source of the "corrected" sequence of the instant application is noted. However it is still not clear and applicants response provides no evidence that the "error in the prior art sequence" was or was not directed to corrections of sequencing error. Applicant is directed to page 25, lines 8-24, where the context strongly supports the assumption that the difference of sequence between the prior art and the instant SEQ ID NO: 1 was due to sequencing error.

Claims 19 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635

srm

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